Összefoglalás a 174/2015/FOR ügyről, amelyben a Bizottság állítólag elmulasztotta kivizsgálni a PIP mellimplantátumok eltávolításának biztonságosságáról szóló jelentés elfogadásával kapcsolatos összeférhetetlenséget - 174/2015/FOR. sz. ügyben hozott határozata

Határozat
Ügy 174/2015/FOR - **Vizsgálat megindítása** 26/02/2015 - **Határozat** 27/10/2015 - **Érintett intézmények** Európai Bizottság (Az intézmény rendezte) |

A vizsgálat egy feltételezett összeférhetetlenséggel foglalkozott a PIP mellimplantátumok eltávolításának kockázatairól szóló jelentés elkészítésére összehívott európai bizottsági tudományos bizottság egy tagja esetében.

2010-ben derült ki, hogy egy orvostechnikai eszközöket gyártó francia vállalat (PIP) 2001 óta orvosi szilikon helyett ipari szilikonból készült mellimplantátumokat állított elő és árusított illegálisan. A PIP-botrány a PIP implantátumok betiltásához és a PIP ügyvezető igazgatójának bebörtönzéséhez vezetett. Becslések szerint világszerte 400 000 nő esett áldozatul a PIP-botránynak.

Az Európai Bizottság 2012-ben kérte fel az új és újonnan azonosított egészségügyi kockázatok tudományos bizottságát, hogy készítsen jelentést a PIP implantátumok biztonságosságáról, különös tekintettel arra a kérdésre, hogy a Bizottság javasolja-e a PIP implantátumok megelőzési célú műtéti eltávolítását.

A panaszos, a PIP-botrány áldozatait képviselő NGO (nem kormányzati szervezet) nem volt megelégedve a tudományos bizottság 2014-es jelentésében megfogalmazott különféle következtetésekkel. Azt állította, hogy a Bizottság tudományos bizottságát segítő munkacsoport egyik tagja esetében összeférhetetlenség áll fenn, ezért nem lett volna szabad részt vennie a jelentés elkészítésében. A panaszos emiatt a jelentés visszavonását kérte. Ez a vizsgálat csak az állítólagos összeférhetetlenség kérdésével foglalkozik. A jelentés tudományos következtetéseit nem vizsgálja.

Az ombudsman megvizsgálta az állítólagos összeférhetetlenség kérdését, és azt állapította meg, hogy az érintett szakértő eleinte nem vallotta be az összes érdekeltségét. Amikor azonban a Bizottság felkérte, hogy mutassa be az összeférhetetlenségének hiányát igazoló megfelelő információkat, ennek eleget tett. Az ombudsman azt állapította meg, hogy a Bizottság az

újonnan benyújtott információk vizsgálata után helyesen jutott arra a következtetésre, hogy a szakértő esetében nem áll fenn összeférhetetlenség.

Az ombudsman mindazonáltal úgy találta, hogy a panaszos joggal aggódott, amikor felfedezte, hogy a Bizottság eleinte nem rendelkezett az ahhoz szükséges információkkal, hogy állást foglaljon a szakértő függetlenségéről. Az ombudsman ezért több javaslatot tett arra nézve, hogy a Bizottság hogyan tudna javítani az ilyen információk összegyűjtésén és elemzésén.

The background to the complaint

1. The complainant is a group, the PIP Action Campaign, campaigning to protect women who are victims of the Poly Implant Prothèse breast implants scandal. Poly Implant Prothèse or PIP was a French company that produced silicone-gel breast implants. In 2010, it was revealed that it had, since 2001, illegally manufactured and sold breast implants made from industrial-grade silicone instead of from medical-grade silicone. It is estimated that 400 000 women worldwide were victims of the PIP implant scandal.

2. The complaint relates to a report on the risks of the PIP implants, produced by the European Commission's Scientific Committee on Emerging and Newly Identified Risks (SCENIHR) [1] . SCENIHR forms part of the Advisory Structure of Scientific Committees, established to advise the Commission in areas of consumer safety, public health and the environment. SCENIHR is composed of 14 members. For each subject of study it establishes a Working Group, composed of one SCENIHR member and external experts. Upon request of the Commission, more specifically the Directorate General for Health and Food Safety (DG SANCO) [2] , a Working Group was established in 2012 to examine the safety of PIP implants. It focused, in particular, on whether it should recommend the preventative surgical removal of PIP implants.

3. The complainant wrote to DG SANCO on 7 May 2014 informing it of what it called a "breach of trust" by a member of the PIP Working Group. It stated that one of the external experts of the Working Group failed to declare, in his declaration of interests submitted to the Commission, that he owned a biomedical company and that his research was funded by a large consumer goods multinational. The complainant alleged that these interests are linked to the toxicological determination of some chemical substances found in PIP implants. It therefore asked for the expert to be removed from the Working Group. The Commission replied that it would examine this information.

4. The SCENIHR Final opinion on the safety of PIP implants was published a few days later. Its findings were, essentially, that the risks associated with PIP implants did not justify the risks of surgically removing them, except where there was already a rupture or leak in the implant [3] .

5. Shortly thereafter, the complainant wrote to the Commission, criticising it for publishing the Final opinion despite the concerns regarding the independence of one of the external experts who worked on the Final opinion. It asked the Commission to withdraw the Final opinion and to

investigate fully the independence of the expert concerned. In its reply, the Commission stated that it had looked into the allegation and found that the expert was not in a conflict of interests. It therefore found no reason to withdraw the opinion.

6. The complainant then met with the Commission in September 2014. It also wrote to it again. It stated that the expert's declaration of interests had not been published proactively by the SCENIHR. It also noted that the expert had failed to declare his connections with some companiesvarious national regulatory bodies and associations. It added that the research, carried out at the university where he works as a professor, has been used to support the application for licencing of breast implants in the past. The complainant therefore repeated its argument that the determination of chemical toxicity of PIP implants was linked to his financial interests.

7. The complainant then turned to the Ombudsman.

The inquiry

8. The Ombudsman opened an inquiry into the complaint and identified the following allegation and claim:

Allegation:

The Commission failed to ensure that there were no conflicts of interests relating to an expert providing advice to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

Claim:

The Commission should ensure that the SCENIHR is independent.

9. In the course of the inquiry, the Ombudsman's services inspected the Commission's files. Those files which were not marked as confidential were sent to the complainant, along with the preliminary conclusions of the Ombudsman's services relating to the inspected documents. That preliminary conclusion was that there was no maladministration by the Commission. The complainant submitted observations on the inspection report, the additional documents and the preliminary conclusions. It also provided the Ombudsman with additional information. The Ombudsman did not consider it necessary to ask the Commission to submit an opinion on the allegation.

Allegation of a conflict of interest relating to an expert advising the SCENIHR

Arguments presented to the Ombudsman

10. In its observations on the inspection report, the complainant repeated its view that the expert had failed to declare all of his interests, namely his connections to several companies, including his own biomedical company. Furthermore, he had failed to declare his role on various public bodies. The complainant added that the university where the expert worked had links to the breast implant manufacturing industry since its research was used to support the licensing request for the sale of Cereplas/Cereform breast implants in Australia.

11. The complainant also alleged that the Final opinion is erroneous and lacks conclusions on certain cyclic siloxanes (such as D4 [4]), present in PIP implants. According to the complainant, even though these chemicals are toxic, their toxicity was allegedly disregarded by the SCENIHR opinion. The complainant also noted in this sense that the expert in question had links to some consumer goods companies that lobby to influence the regulation of D4 and other cyclic siloxanes.

12. The complainant also repeated its general disagreement on the scientific conclusions set out in the SCENIHR Final opinion.

The Ombudsman's assessment

13. The Ombudsman fully understands the fear, anxiety and frustration of the women who have been the victims of PIP implants. She is also of the view that the complainant's campaign to protect the interests of these victims is of utmost importance. She recognises that the complainant raised many legitimate concerns in its correspondence with the Commission, the independence of the SCENIHR being one of them.

14. The Ombudsman notes, as a preliminary point, that the Commission argued in its correspondence with the complainant that the role of the expert whose independence was challenged was minor and that this, together with the collegiate nature of both the Working Group and the SCENIHR, was a safeguard which helped mitigate possible conflicts of interests.

15. The Ombudsman stresses that the independence of any working group can only be guaranteed if there is no doubt as to the independence of each member of the working group including **each of the external experts** . The independence of such persons is of paramount importance given the role of SCHENIHR to evaluate emerging and newly identified risks to human health and given that the role of scientific experts is a key element of that decision-making process. This is reflected in the relevant Rules of Procedure, according to which both the SCENIHR members and the external experts " *shall undertake to act independently from any external influence* ." [5] While these comments are relevant as regards all such scientific working groups, they are of particular importance in areas where citizens' interests are significantly affected by the work of such groups. The SCENIHR is often entrusted with presenting opinions on very sensitive and important issues, the safety of PIP implants being one of them. The Ombudsman is thus convinced that enhancing the independence, and

the transparency and accountability, of the SCENIHR and its working groups, would lead to greater public trust in the SCENIHR's work. It is also to be expected that any failures in this regard may give rise to public mistrust and even fear.

The alleged conflict of interests

16. The complainant informed the Commission of its concerns as regards the independence of one of the experts that contributed to the Final opinion a few days before the publication of the Final opinion. The Commission inquired into the matter and informed the complainant of its position thereon only after the Final opinion had already been published. Given the importance and the sensitivity of the subject matter of the Final Opinion and the legitimate concerns of the complainant, the Ombudsman finds it regrettable that the Commission did not consider it appropriate to postpone the publication of the Final opinion until it had checked on the independence of the experts in question and informed the complainant of its position thereon.

17. After contacting the expert to ask him for his views relating to the complainant's concerns, the Commission noted that the expert did indeed carry out occasional consultancy work alongside his work at a major university. However, the Commission noted in its letter of 17 July 2014, he had never conducted consultancy work on PIP breast implants, or on any other model or make of breast implants. It added that he had never undertaken any consultancy work on silicones or siloxanes. In addition, as regards his links to a large consumer goods multinational which funded research carried out in the expert's university department, the Commission noted that the " *research focused on "allergic dermatitis and has no relationship with PIP breast implants, other breast implants, silicones or siloxanes.* "

18. The Ombudsman has inspected the Commission files and can confirm that the above information indeed summarizes the content of correspondence between the expert and the Commission. In brief , the correspondence between the Commission and the expert reports that the expert **never worked on PIPs or other types of breast implants for any private entity** . His work on the SCENIHR Final opinion could not therefore have been influenced by any financial or other incentives **from companies in the breast implant sector** .

19. The complainant has also expressed doubts as to the expert's independence as regards giving advice on the toxicity of specific chemicals found in PIP breast implants, namely D4 and other cyclic siloxanes. The complainant states that the expert has provided consultancy services to multinational companies that produce cosmetics. The complainant noted that these companies lobbied for the classification of D4 and other cyclic siloxanes as non-toxic and not dangerous. In the complainant's view, the expert's previous work for these companies affected his capacity to give independent advice on the toxicity of cyclic siloxanes that are contained in PIP implants.

20. The Ombudsman notes that she has seen no evidence that the expert provided any advice to any cosmetic company on the specific issue of cyclic siloxanes. Neither has the Ombudsman seen any evidence that the expert provided any advice to any company that produces or uses

cyclic siloxanes.

21. As regards the expert's links with the consumer goods company funding his university research, it should be noted that this relationship is far less direct than his consultancy work for companies, since the funding is received by the university where he is employed, and not by him directly. There is, in any event, no evidence that the company concerned produces or markets siloxanes.

22. The complainant states that the company that funds the university research is, even if it does not itself produce or market siloxanes, a member of "Cosmetics Europe group" [6] . The complainant asserts that this group has interests in declaring siloxanes non-toxic. However, the Ombudsman notes, this group is a broad umbrella group representing over 4000 member companies and associations of different sizes in the cosmetics and personal care industry. The fact that some of these other 4000 companies might produce or market siloxanes does not imply, in any way, that the company that funds the expert's university research has an interest in siloxanes. By extension, this fact does not in any way imply that the expert's independence was compromised through the funding of his university by this company.

23. In conclusion, the Ombudsman finds no basis to call into question the Commission's view as to the independence of the expert.

Duty of external experts to declare all their interests

24. Regardless of this conclusion set out in paragraph 24 above, the Ombudsman has serious concerns as regards the Commission's general approach to the issue of experts declaring their interests.

25. It is important to draw a clear distinction between an **obligation to declare interests** and **an obligation to declare conflicts of interests** . Of course, an expert should inform the Commission if he or she considers that any of his or her interests might give rise to a conflict of interests. However, the assessment, as to whether a person's interests could give rise to a conflict of interests, **should never be left only to the person whose independence is being scrutinised** . Relying only on a system of self-assessment can never guarantee the independence of experts. The assessment of the Commission can only be thorough and reliable if the expert in question is requested to provide **a complete list of his interests** so as to allow the Commission to take a view as regards whether any of those interests give rise to a conflict of interests. If the Commission does not require the person who is being scrutinised to disclose **all of his interests** , the Commission will not be able to take a view as regards whether any of those interests give rise to a conflict of interests.

26. The relevant Rules of Procedure support this view. They state that *"Scientific Advisors and external experts shall make in writing a specific declaration of interest when accepting to participate in any of the activities of the Advisory Structure"* [7] . The Rules of Procedure demand the disclosure of **interests** and not of **conflicts of interest** . The Rules specifically

illustrate the difference between the two categories by stating that " *an interest declared is not automatically considered to create a conflict of interests* " [8] . Similarly, the Rules of Procedure also state that the external experts are *"under a continuing duty to declare before undertaking* **any activity, situation, circumstance or other fact potentially involving a direct or indirect interest** *[...], in order to allow the Scientific Committee and/or the Commission* **to identify those interests which might be considered prejudicial to the independence of the member, advisor or external expert** *"* [9] .

27. Despite the clarity of the Rules of Procedure, it appears that the expert concerned in the present case was not sufficiently aware of the need to declare all his interests. On the basis of the above, the Ombudsman suggests that the Commission considers redrafting its current Guidance to Declarations of Interests [10] to ensure that it is even clearer to experts that they should make complete declarations of **all their interests** and not only those interests which the experts believe would give rise to conflicts of interests, thereby ensuring that the Commission can make thorough assessments of the independence of experts.

Additional observations

28. The complainant has, in its complaint and observations, clearly expressed its disagreement with many aspects of the Final opinion. The complainant has already been informed that the Ombudsman cannot take a position on an issue of science except in the case of an error of assessment that was so manifest as to be evident to a non-expert reader. The Ombudsman did not find such evident errors and thus concluded there are not sufficient grounds to open an inquiry on this specific issue.

29. However, given the sensitivity of the issue with which the Final opinion has dealt, the Ombudsman urges the Commission to closely follow possible new scientific data in this particular area, in order to ensure that its position is as accurate and up-to-date as possible.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion and further remarks:

The Commission has, by inquiring in the complainant's concerns, verified there was no conflict of interest and has thus settled the matter.

The complainant and the Commission will be informed of this decision.

Further remarks

The Commission should verify the independence of both the SCENIHR members and the external experts on the basis of a complete declaration of interests when they are appointed.

There should be no differences in the substance of declarations of interests for SCENIHR members and external experts. The Commission should require external experts to give a "written declaration which has a broad scope and describes all the interests that could conceivably give rise to a conflict".

The same principles should be applied to the Scientific Committees on Consumer Safety (SCCS) and Health and Environmental Risks (SCHER).

The Commission should continue to evaluate new scientific data relating to the safety of PIP implants.

Emily O'Reilly

27/10/2015

[1] The Commission Decision 2008/721/EC of 5 September 2008 set up an advisory structure of Scientific Committees and experts to advise the Commission in the field of consumer safety, public health and the environment. One of the Committees is the SCENIHR which deals with questions related to emerging or newly identified health and environmental risks.

[2] DG SANCO was renamed in DG SANTE in 2015.

[3] The SCENIHR Final opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants can be found here: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_043.pdf [Link]

[4] Octamethylcyclotetrasiloxane, or D4, is an organosilicon compound. It presents as a colourless viscous liquid.

[5] Rules of Procedure for the Scientific Committees on Consumer Safety (SCCS), Health and Environmental Risks (SCHER) and Emerging and Newly Identified Health Risks (SCENIHR), paragraph 18, available at: http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_2013_en.pdf [Link].

The issue of the independence of experts called upon to give advice to such specialised scientific Committees, such as the SCCS, the SCHER and the SCENIHR, should be distinguished from the issue of experts forming part of "expert groups" which assist the Commission in the development of EU legislation and policy. While experts appointed to assist the SCENIHR must be independent, and should thus have no role as a "representative" of a particular sector, experts appointed to "expert groups" may come from and work with sectoral interests, such as industry and specialised NGOs. The issue that arises in relation to such

"expert groups" is whether the composition of such groups is sufficiently balanced and transparent to ensure that they are not dominated by corporate interests or other sectoral interests. See http://www.ombudsman.europa.eu/en/press/release.faces/en/58870/html.bookmark [Link]

[6] The website of this group is https://www.cosmeticseurope.eu [Link]

[7] Paragraph 20 of the Rules of Procedure.

[8] Paragraph 5 of Annex II to the Rules of Procedure.

[9] Paragraph 21 of the Rules of Procedure.

[10] Annex II to the Rules of Procedure.